

Listing of the Claims:

1. (currently amended) A sterilized An irradiated polymeric material comprising a plurality of substantially non-aggregated microparticles, for use in a body of a mammal wherein said polymeric material is sterilized by irradiation at a temperature below 25 °C wherein the irradiated polymeric material is selected from the group consisting of an implant, a device, a suture, and a delivery system.
2. (currently amended) The irradiated sterilized polymeric material of claim 1 which further comprises a therapeutically active agent.
3. (currently amended) The irradiated sterilized polymeric material of claim 40 [[1]] wherein said temperature is at or below about 5 °C.
4. (currently amended) The irradiated sterilized polymeric material of claim 1, wherein the microparticles comprise polymeric microspheres 2 which comprises polymeric microspheres, microparticles, microcapsules, or implants.
5. (currently amended) The irradiated sterilized polymeric material of claim 1, wherein the microparticles comprise polymeric microcapsules 2 which comprises polymeric microspheres, microparticles, or microcapsules.
6. (canceled)
7. (currently amended) The irradiated sterilized polymeric material of claim 1 [[5]] which comprises polylactide-co-glycolide or polylactic acid.

8. (currently amended) The irradiated sterilized polymeric material of claim 1 [[5]] which comprises polylactide-co-glycolide.

9. (currently amended) The irradiated sterilized polymeric material of claim 40 [[5]] wherein said temperature is below about 15 °C.

10. (currently amended) The irradiated sterilized polymeric material of claim 40 [[5]] wherein said temperature is below about 10 °C.

11. (currently amended) The irradiated sterilized polymeric material of claim 40 [[5]] wherein said composition temperature is at or below about 5 °C.

12. (currently amended) The irradiated sterilized polymeric material of claim 40 [[5]] which is sterilized by gamma irradiation at a dose of about 1.5 to about 4.0 mRad.

13. (currently amended) The irradiated sterilized polymeric material of claim 2 [[5]] wherein said therapeutically active agent comprises a retinoid, a prostaglandin, a tyrosine kinase inhibitor, a glucocorticoid, an androgenic steroid, an estrogenic steroid, a non-estrogenic steroid, an intracellular adhesion molecule inhibitor or an alpha-2-adrenergic agonist.

14. (currently amended) The irradiated sterilized polymeric material of claim 2 [[5]] wherein said therapeutically active agent comprises a retinoid.

15. (currently amended) The irradiated sterilized polymeric material of claim 2 [[5]] wherein said therapeutically active agent comprises tazarotene.

16. (currently amended) A method of sustained delivery of a therapeutically active agent to a mammal comprising administering the polymeric material of claim 2, wherein said polymeric material is sterilized sterilized polymeric material comprising said therapeutically active agent to said mammal, wherein the polymeric material is sterilized by irradiation at a temperature below 25 °C.

17. (currently amended) The method of claim 16 wherein the polymeric material is sterilized by irradiation comprising sterilization by irradiation comprises gamma irradiation.

18. (currently amended) The method of claim 17 wherein said irradiation is conducted at a temperature is below about 15 °C.

19. (currently amended) The method of claim 17 wherein said irradiation is conducted at a temperature is below about 10 °C.

20. (currently amended) The method of claim 17 wherein said irradiation is conducted at a temperature is below about 5 °C.

21. (currently amended) The method of claim 17 wherein said irradiation is conducted at a temperature [[is]] from -25°C to 5 °C.

22. (original) A method of sterilizing a polymeric material for use in a body of a mammal comprising irradiating said polymeric material at a temperature below 25 °C.

23. (original) The method of claim 22 wherein the polymeric material further comprises a therapeutically active agent.

24. (original) The method of claim 22 wherein said temperature is below about 15 °C.

25. (original) The method of claim 22 wherein said temperature is below about 10 °C.

26. (original) The method of claim 22 wherein said temperature is below about 5 °C.

27. (currently amended) A composition comprising a sterilized plurality of sterilized polymeric microparticles and a therapeutically active agent for use in a body of a mammal wherein said sterilized plurality polymeric material is sterilized by irradiation of an unsterilized plurality of polymeric microparticles with external cooling of said unsterilized plurality polymeric material during sterilization.

28. (original) The composition of claim 27 wherein said composition is suitable for sustained delivery of said therapeutically active agent.

29. (currently amended) The composition of claim 27 wherein the temperature of said sterilized plurality of polymeric microparticles material at the end of the sterilization process is about 10 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

30. (currently amended) The composition of claim 27 wherein the temperature of said sterilized plurality of polymeric microparticles material at the end of the sterilization process is about 20 °C to about 50 °C lower than said temperature would be in the absence of external cooling.

31. (currently amended) The composition of claim 27 wherein the temperature of said sterilized plurality of polymeric microparticles material at the end of the sterilization process is about 50 °C or more lower than said temperature would be in the absence of external cooling.

32-39. (canceled).

40. (new) The irradiated polymeric material of claim 1, wherein the polymeric material is sterilized by irradiation at a temperature below 25 °C.

41. (new) The irradiated polymeric material of claim 1 being sterilized.

42. (new) The irradiated polymeric material of claim 1, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle.

43. (new) The irradiated polymeric material of claim 1, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 70% of the microparticles are not in contact with another microparticle.

44. (new) The irradiated polymeric material of claim 1, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 80% of the microparticles are not in contact with another microparticle.

45. (new) The irradiated polymeric material of claim 1, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 90% of the microparticles are not in contact with another microparticle.

46. (new) The irradiated polymeric material of claim 1, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle at the time the suspension is administered to a patient.

47. (new) The irradiated polymeric material of claim 1, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 7.4 um.

48. (new) The irradiated polymeric material of claim 1, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 8.4 um in diameter.

49. (new) The irradiated polymeric material of claim 1, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 13.5 um in diameter.

50. (new) A sterilized polymeric implant comprising a plurality of substantially non-aggregated microparticles.

51. (new) The sterilized polymeric implant of claim 50, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle.

52. (new) The sterilized polymeric implant of claim 50, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 70% of the microparticles are not in contact with another microparticle.

53. (new) The sterilized polymeric implant of claim 50, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 80% of the microparticles are not in contact with another microparticle.

54. (new) The sterilized polymeric implant of claim 50, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 90% of the microparticles are not in contact with another microparticle.

55. (new) The sterilized polymeric implant of claim 50, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle at the time the suspension is administered to a patient.

56. (new) The sterilized polymeric implant of claim 50, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 7.4 um.

57. (new) The sterilized polymeric implant of claim 50, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 8.4 um in diameter.

58. (new) The sterilized polymeric implant of claim 50, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 13.5 um in diameter.

59. (new) A plurality of substantially non-aggregated sterilized microparticles.

60. (new) The plurality of claim 59, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle.

61. (new) The plurality of claim 59, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 70% of the microparticles are not in contact with another microparticle.

62. (new) The plurality of claim 59, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 80% of the microparticles are not in contact with another microparticle.

63. (new) The plurality of claim 59, wherein the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 90% of the microparticles are not in contact with another microparticle.

64. (new) The plurality of claim 59, whercin the plurality of substantially non-aggregated microparticles are suspended in an emulsion, and more than 50% of the microparticles are not in contact with another microparticle at the time the suspension is administered to a patient.

65. (new) The plurality of claim 59, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 7.4 um.

66. (new) The plurality of claim 59, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 8.4 um in diameter.

67. (new) The plurality of claim 59, wherein a difference in a diameter of the particles in 90% of the plurality of substantially non-aggregated microparticles is less than about 13.5 um in diameter.

68. (new) A sterilized polymeric material produced by a process comprising sterilizing an unsterilized plurality of microparticles using the method of claim 24 to produce a sterilized plurality of microparticles, wherein said sterilized plurality of microparticles is less aggregated than a plurality of microparticles produced by a process comprising sterilizing said unsterilized plurality of microparticles using a method identical to that of claim 24 except that the irradiation of said unsterilized plurality of microspheres is conducted at 25 °C.

69. (new) A sterilized polymeric material produced by a process comprising sterilizing an unsterilized plurality of microparticles using the method of claim 26 to produce a sterilized plurality of microparticles, wherein said sterilized plurality of microparticles is less aggregated than a plurality of microparticles produced by a process comprising sterilizing said unsterilized plurality of microparticles using a method identical to that of claim 26 except that the irradiation of said unsterilized plurality of microspheres is conducted at 25 °C.